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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,444	01/22/2002	Paul M. Guyre	DC-0172	9998

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,444	GUYRE ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *Three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 and 3 are pending.

2. In view of the amendment filed 12/22/03, the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling only for a compound comprising a baculovirus expressed recombinant Fel dI wherein the baculovirus expressed recombinant Fel dI comprises a sFv humanized anti-CD64 monoclonal antibody H22 fused to Fel dI chain 1 and Fel dI chain 2 wherein chain 1 and chain 2 are linked in series by a glycine/serine linker encoded by SEQ ID NO: 5 as shown in Figure 1 for diagnosis of cat allergy, **does not** reasonably provide enablement for *any* compound as set forth in claims 1 and 3 for diagnosis and treatment of cat allergy. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in **scope** with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention. The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation.

The specification discloses only a compound as shown in Figure 1 wherein the compound comprising a baculovirus expressed recombinant Fel dI wherein the baculovirus expressed recombinant Fel dI comprises a sFv humanized anti-CD64 monoclonal antibody H22 fused to Fel dI chain 1 and Fel dI chain 2 wherein chain 1 and chain 2 are linked in series via a flexible peptide linker a glycine/serine linker $(glycine_4\,Ser)_3$ encoded by SEQ ID NO: 5 and further linked

to Myc or His tag for diagnosis of cat allergy in humans. The recombinant Fel dI is purified on nickel affinity column. The rFel dI shows that IgG and IgE antibody binding is identical to natural Fel dI using IgG antibody in pooled sera from either Japanese or US cat allergic patients.

The specification does not teach how to make and use *any* compound mentioned above for diagnosing or treating cat allergy because there is insufficient guidance on the hybridization conditions using primers of SEQ ID NO: 1-4 along with the template pET11dΔHR chain-1 *Feld* I and pET11dΔHR chain-2 *Feld* I to amplifying the nucleic acid sequences that encoded the Fel dI chain 1 and chain 2 in the claimed compound. Further, there is insufficient guidance as to the structure of nucleic acid sequence encoding Fel dI chain 1 and Fel dI chain 2 expressed in series and linked together by a glycine serine linker.

The state of the prior art as exemplified by Wallace *et al* and Sambrook *et al* is such that determining the specificity of hybridization probes is empirical by nature and the effect of mismatches within an oligonucleotide probe is unpredictable. Since the hybridization conditions amplifiable by PCR using the primers for making the claimed compound are not disclosed, it follows that claimed compound is not enabled. It also follows that any compound further comprising a sFv of monoclonal antibody H22 that is humanized anti-CD64 antibody is not enable.

For these reasons, it would require undue experimentation of one skilled in the art to practice the claimed invention. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In re wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the decision of the court indicates that the more unpredictable the area is, the more specific enablement is necessary. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

Applicants' arguments filed 12/22/03 have been fully considered but are not found persuasive.

Applicants' position is that the skilled artisan could readily produce the nucleic acid sequence encoding Fel dI chain 1 and chain 2 using the guidance provided by the specification and it is well known in the art of non-degenerate PCR methodologies to synthesize compounds of claims 1 and 3.

However, the specification as filed does not provide guidance for the structure, i.e., the amino acid sequence or the nucleic acid sequence encoding the claimed compound. Although the specification provides guidance for the primers of SEQ ID NO: 1-4 to be use along with the template pET11dΔHR chain-1 *Feld* I and pET11dΔHR chain-2 *Feld*, the hybridization condition used by applicant is not disclosed. Until the hybridization condition is disclosed and the structure of the claimed compound is taught in the specification, it would take an undue amount of experimentation for one skilled in the art to practice the claimed invention.

5. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* compound as set forth in claims 1 and 3 for diagnosis and treatment of cat allergy.

The specification discloses only a compound as shown in Figure 1 wherein the compound comprising a baculovirus expressed recombinant Fel dI wherein the baculovirus expressed recombinant Fel dI comprises a sFv humanized anti-CD64 monoclonal antibody H22 fused to Fel dI chain 1 and Fel dI chain 2 wherein chain 1 and chain 2 are linked in series via a flexible peptide linker a glycine/serine linker $(glycine_4 Ser)_3$ encoded by SEQ ID NO: 5 and further linked to Myc or His tag for diagnosis of cat allergy in humans. The recombinant Fel dI is purified on nickel affinity column. The rFel dI shows that IgG and IgE antibody binding is identical to natural Fel dI using IgG antibody in pooled sera from either Japanese or US cat allergic patients.

The specification does not teach the specific PCR condition using primers 1-4 to amplify any nucleic acid sequences that encoded Fel dI chain 1 and chain 2. Further, claim 1 recites more than one nucleic acid sequences encoding chain 1 or chain 2 which are amplifiable by the specific set of primers. However, the specific nucleic acid sequences encoding chain 1 and chain 2 are not adequately described, in addition to the PCR condition. Given the indefinite number of undisclosed nucleic acid sequences and PCR condition for making the claimed compound, the compound as set forth in claim 1 is not adequately described. Since the compound in claim 1 is not adequately described, it follows that the undisclosed compound further comprising a sFv of monoclonal antibody H22 that is a humanized anti-CD64 antibody is not adequately described.

Given the lack of a written description of *any* additional representative species of nucleic acid sequences that encoded Fel dI chain 1 and chain 2 in the claimed compound, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicants' arguments filed 12/22/03 have been fully considered but are not found persuasive.

Applicants' position is that the skilled artisan could readily produce the nucleic acid sequence encoding Fel dI chain 1 and chain 2 using the guidance provided by the specification and it is well known in the art of non-degenerate PCR methodologies to synthesize compounds of claims 1 and 3.

However, there is insufficient written description about the structure such as the amino acid sequence and the nucleic acid sequence encoding the claimed compound. Although the specification discloses the primers of SEQ ID NO: 1-4 to be use along with the template pET11dΔHR chain-1 *Feld* I and pET11dΔHR chain-2 *Feld*, the hybridization condition used by applicant is not disclosed.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

9. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 5, 2004

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